

# Notice of Allowability

Application No.

09/926,256

Examiner

Anand U. Desai, Ph.D.

Applicant(s)

FUKUCHI ET AL.

Art Unit

1656

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to February 5, 2007.
2. ☒ The allowed claim(s) is/are 1, 2, 4, 5, and 7-10.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on February 5, 2007. Claim 3 has been cancelled. Claims 11-15 have been withdrawn previously. Claims 1, 2, and 4-10 are currently under examination.

### **Withdrawal of Rejections**

2. The rejection of claims 1, 2, and 4-10 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn.
3. The rejection of claims 1, 2, and 4-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

### **EXAMINER'S AMENDMENT**

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Vincent Shier on May 11, 2007.

Examiner's amendment to the claims:

Please replace Claim 1 with the following:

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Claim 1. A method for purifying the  $\alpha$ -subunit originating from an oligomeric protein *Crotalus horridus horridus* B (CHH-B) having disulfide bonds within a subunit and between subunits, which comprises:

(a) refolding the  $\alpha$ -subunit by denaturing the oligomeric protein or its  $\alpha$ -subunit in a solution comprising a reducing agent and a protein-denaturing agent and removing the reducing agent and the denaturing agent from the solution in the presence of polyoxyalkyl polyether having a functional group that reacts with a thiol group to allow the  $\alpha$ -subunit to bind to the polyoxyalkyl polyether via the reaction between the thiol group of the  $\alpha$ -subunit and the functional group of the polyoxyalkyl polyether that reacts with a thiol group; and

(b) isolating the  $\alpha$ -subunit of the *Crotalus horridus horridus* B (CHH-B) that is bonded to the polyoxyalkyl polyether from the solution.

In claim 2, replace, "wherein the subunit peptide", with ---wherein the  $\alpha$ -subunit---.

In claim 5, replace, "wherein the subunit peptide", with ---wherein the  $\alpha$ -subunit---.

Claim 6. (Cancelled).

In claim 7, replace, "arises from a subunit peptide", with ---arises from the  $\alpha$ -subunit---.

In claim 8, replace, "the subunit peptide", with ---the  $\alpha$ -subunit---.

In claim 9, replace, "the subunit peptide", with --- the  $\alpha$ -subunit---.

In claim 10, replace, "the subunit peptide, with --- the  $\alpha$ -subunit---.

Claims 11-15. (Cancelled).

***Allowable Subject Matter***

5. Claims 1, 2, 4, 5, and 7-10 are allowed.
6. The following is an examiner's statement of reasons for allowance: The claims of the application are limited to the method of purifying the  $\alpha$ -subunit of the *Crotalus horridus horridus* B (CHH-B) protein, because the prior art of record does not disclose the utility for the  $\beta$ -subunit of *Crotalus horridus horridus* B (CHH-B) protein. The prior art discloses the use of *Crotalus horridus horridus* B (CHH-B) protein as an anti-thrombotic. Applicants disclose the use of the  $\alpha$ -subunit of the *Crotalus horridus horridus* B (CHH-B) protein conjugated with a polyoxyalkyl polyether as having reduced antigenicity and capable of binding to a glycoprotein on platelets to inhibit the downstream thrombosis event.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

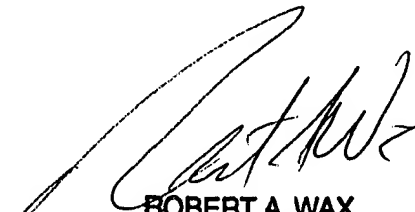
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 11, 2007  
Anand Desai



ROBERT A. WAX  
PRIMARY EXAMINER